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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/484,886	01/18/2000	Gale E. Smith	674506-2035.2	1236

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EXAMINER	
SRIVASTAVA, KAILASH C	
ART UNIT	PAPER NUMBER
1657	
MAIL DATE	DELIVERY MODE
02/20/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/484,886	SMITH ET AL.	
	Examiner	Art Unit	
	KAILASH C. SRIVASTAVA	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *96-116 and 127-131* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *96-116 and 127-131* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Request for continued examination (i.e., R.C.E.) under 37 C.F.R. §1.114, including the fee set forth in 37 C.F.R. §1.17(e), was filed in this application on 31 October 2007 after a Final action was mailed on 02 May 2007. Since this application is eligible for continued examination under 37 C.F.R. §1.114, and the fee set forth in 37 C.F.R. §1.17(e) has been timely paid, the finality of the previous Office action mailed 02 May 2007 has been withdrawn pursuant to 37 C.F.R. §1.114. Applicants' submission filed 31 October 2007 has been entered. Accordingly an R.C.E. has been established and the action on R.C.E. follows.

2. Response and amendment filed 31 October 2007 to the Office Action mailed 02 May 2007 is acknowledged and entered.

General Informal Matters

3. Please note, as indicated at item 4 of the office Action mailed 02 May 2007, the Art Unit Location for your application under prosecution at the United States Patent and Trademark Office (i.e., USPTO) has been changed to Art Unit 1657. To aid in correlating any papers for this application (i.e., 09/484,886), all further correspondence regarding this application should be directed to Examiner Kailash C. Srivastava in Art Unit 1657.

Withdrawals In View of Arguments

4. In view of remarks filed 31 October 2007 to the Office Action mailed 02 May 2007, the objections made to Claims 96-116 and 127-129 in the Office Action mailed 02 May 2007 are hereby withdrawn.

Claims Status

5. Claims 1-95 and 117-126 have been cancelled.

6. Claims 130-131 have been added.

7. Claims 96-100, 103 and 127-129 have currently been amended.

8. Claims 96-116 and 127-131 are pending and are examined on merits.

Objection to Claims – Minor Informalities

9. In view of amendments filed 31 October 2007, following are new objections to Claims 97-116 and 127-129 and to newly presented Claims 130-131.

10. Claims 96-116 and 127-131 are objected to because of the following informalities:

- As currently worded in amended Claim 96 the phrase, "(ii) an activity of at least 200,000 U/mg protein or of about 500,000 U/mg protein" does not clarify where said activity of said U/mg protein exists? *In vivo*, or *in vitro* or some where else? If the activity is *in vivo*, it should be stated that said activity is *in vivo*.

- Each of Claims 98-100 are objected to because a space is missing between "," and the word, "produced" at line two of each of Claims 98-100. Appropriate correction is required.

- Each of Claims 111-116 are objected to because at Line one of each one of Claims 111-116, before the word "wherein" a --, -- should be inserted. Appropriate correction is required.

- As currently worded in amended Claim 127 the phrase, "(ii) a specific activity of greater than 200,000 U/mg protein does not clarify where said activity of said U/mg protein exists? *In vivo*, or *in vitro* or some where else. If the activity is *in vivo*, it should be stated that said activity is *in vivo*.

- As currently worded in amended Claim 128 the phrase, "(ii) a specific activity of between 200,000 U/mg protein and 500,000 U/mg protein" does not clarify where said activity of said U/mg protein exists? *In vivo*, or *in vitro* or some where else. If the activity is *in vivo*, it should be stated that said activity is *in vivo*.

- As currently worded in amended Claim 129 the phrase, "(ii) a specific activity of greater than 500,000 U/mg protein" does not clarify where said activity of said U/mg protein exists? *In vivo*, or *in vitro* or some where else. If the activity is *in vivo*, it should be stated that said activity is *in vivo*.
- As currently worded in each of Claims 130-131 (i) *in vivo* and, "(ii) a specific activity of certain U/mg protein" has been claimed. However, said wording does not clarify where said activity of said U/mg protein exists? *In vivo*, or *in vitro* or some where else. If the activity is *in vivo*, it should be stated that said activity is *in vivo*.

All other claims depend directly from the objected claims (e.g., Claim 99 or 100) and are, therefore, also objected for the reasons set forth above.

ART REJECTIONS

Claim Rejections – 35 U.S.C. § 102

11. The following is a quotation of 35 U.S.C. §102 which forms the basis for all anticipation rejections set forth in this Office action:

> ***A person shall be entitled to a patent unless –***
>
> ***(b)the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.***

12. Claims 96-97, 99-116 and newly presented Claim 130 stand rejected under 35 U.S.C. §102(b) as anticipated by Quelle et al. (Blood. 1989. Volume 74, Pgs. 652-657) with evidence provided by Dorland's Illustrated Medical Dictionary (W. B. Saunders Co., Philadelphia, 1988, Page 581) for the reasons of record, especially the side by side comparison described in the table at Page 5 of the Office Action mailed 02 May 2007.

In response to art rejections under 35 U.S.C. §102(b) discussed *supra*, citing a number of case laws and applying said laws to the art rejection in the Office Action mailed 02 May 2007, applicants argue "Quelle et al. does not contain all the elements of the presently claimed invention ". Applicants reasoning for said argument is: because the claims as amended in the response filed 31 October 2007 "clearly describe an erythropoietin having two separate activities: (i) an *in vivo* activity; and (ii) an "*in vitro* activity of at least 200,000 U/mg. Nothing in Qelle et al. provides for the existence of both the claimed activities" (See Remarks filed 31 October 2007, Page 8, Lines 27-29).

In contrast to applicants' assertion in the response filed 31 October 2007 that nothing in Quelle provides for the existence of both the activities, Quelle et al. teach an erythropoietin having an *in vitro* activity of at least 200,000 U/mg (Quelle et al., Page 652, Column 1, Lines 1-25; Column 2, Line 6; Page 653, Table 1 and Page 654, Column 2, Line 4) and further teach that said erythropoietin is glycosylated , recombinant, having a ≥95 purity and is obtained in cultured insect cells having a baculovirus expression system (See Quelle et al., Page 652, Column 1, Lines 12-13; Page 654, Column 2, Line 4). In regard to said erythropoietin of Quelle et al. having an *in vivo* activity, silence may not be probative. Furthermore,

applicants, quoting Quelle reference have admitted on record that Quelle et al's purified recombinant erythropoietin has little, if any in vivo activity' (See Applicants' response filed June 25, 2003, Page 11, Lines 29-30). Therefore, Quelle et al. is deemed to anticipate the cited claims.

Applicants' arguments filed 31 October 2007 regarding the rejection to Claims 96-97 and 99-116 as anticipatory by Quelle et al. (Blood. 1989. Volume 74, Pgs. 652-657) with evidence provided by Dorland's Illustrated Medical Dictionary (W.B. Saunders Co., Philadelphia, 1988, Page 581)) in the Office Action mailed 02 May 2007 have been fully and carefully considered but are not persuasive for the reasons of record in the Table at Page 5, Lines 17-28 in the Office Action mailed 02 May 2007 and those discussed *supra*.

Claim Rejections Under 35 U.S.C. §103(a)

13. The following is a quotation of 35 U.S.C. §103(a) that forms the basis for all obviousness rejections set forth in this Office action:

> ***(a)A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.***

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. §103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. §1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. §103(c) and potential 35 U.S.C. §102(f) or (g) prior art under 35 U.S.C. §103(a).

15. Claims 96-97, 99-116 and newly presented Claim 130 stand rejected under 35 U.S.C. §103(a) as obvious over Quelle et al. (Blood. 1989. Volume 74, Pgs. 652-657) in view of Dorland's Illustrated Medical Dictionary (W.B. Saunders Co., Philadelphia, 1988, Page 581)

In response to rejections to claims 96-97, 99-116 under 35 U.S.C. §103 (a) cited *supra* in Office Action mailed 02 May 2007, applicants argue that "because Quelle et al., does not contain all the elements of the presently claimed invention, and because Quelle et al., either alone or in combination with any other reference does not provide any teaching, suggestion, motivation or incentive to modify to allow one of skill in the art to arrive at the present invention", Quelle et al., do not render the instantly claimed invention unpatentable/obvious.

In view of the discussion presented in item 14 *supra*, it is clear that Quelle et al. teach a product prepared in the same manner and having the same activity of 200,000 U/mg (See Quelle et al., Page 652, Column 1, Lines 12-13; Page 653, Table 1 and Page 654, Column 2, Line 4) as recited in the instantly claimed invention. Therefore, the product would intrinsically function in the same, or essentially the same manner as in the instantly claimed invention. Instantly claimed higher purity of said erythropoietin is already taught in Quelle et al. Furthermore, said higher purity is deemed merely a matter of judicious selection and routine optimization of a result effective parameter, which is well within the purview of the skilled artisan. Therefore, the product disclosed in Quelle et al. would intrinsically stimulate erythropoietic activity even with"little *in vivo* activity". Note applicants themselves have admitted on record that Quelle et al's purified recombinant erythropoietin has little, if any in vivo activity' (See Applicants' response filed June 25, 2003, Page 11, Lines 29-30).

Applicants' arguments cited *supra* have been fully and carefully considered, but are not persuasive for the reasons of record at Pages 6-9, items 13-15 of the Office Action mailed 02 May 2007 and further for the reasons explained in the preceding paragraph.

In response to applicants' argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, those reasons are cited at Pages 6-9, items 13-15 of the Office Action mailed 02 May 2007 and further for the reasons explained in the preceding paragraph. Furthermore, a rejection under 35 U.S.C. §103 (a) based upon the combination of references is not deficient solely because the references are combined based upon a reason or technical consideration which is different from that which resulted in the claimed invention (*Ex parte Raychem Corp*, 17 U.S.P.Q. 2d 1417).

Conclusion

16. This is a RCE of applicant's earlier Application No. 09484886. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, THIS ACTION IS MADE FINAL even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

17. For the aforementioned reasons, no claims are allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Dr. Kailash C Srivastava/
Examiner, Art Unit 1657

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10 February 2008

/Jon P Weber/
Supervisory Patent Examiner, Art Unit 1657